

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No: 10/730,210
Applicant: Marc Richelsoph
Filed: December 8, 2003
Title: BONE PLATE AND SCREW RETAINING MECHANISM
TC/A.U.: 3775
Examiner: Richard R. Shaffer
Confirmation No.: 2079
Notice of Appeal Filed: January 6, 2009
Docket No.: BBM-141US2

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

S I R :

Appellants hereby request consideration and reversal of the Final Rejection dated October 7, 2008 of claims 1-8, 10, 13-17, 21 and 61.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken or within two months from the date of the Notice of Appeal, whichever is later.

The fees for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2) are provided herewith.

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is Aesculap II, Inc. by virtue of an assignment recorded on April 8, 2005, at Reel/Frame 016427/0959.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences related to the subject matter of this Appeal.

III. STATUS OF CLAIMS

Claims 1-8, 10, 13-17, 21 and 61 are pending, with claims 13 and 14 withdrawn from consideration but dependent on generic claim 1. 1-8, 10, 13-17, 21 and 61 stand finally rejected. Claims 1-8, 10, 13-17, 21 and 61 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

As set forth in the pending independent apparatus claim 1, the presently claimed invention relates to a bone plate assembly utilizing at least one bone screw for fixation of adjacent bones of a spine as generally shown in Figs. 2-5 and 21B.

As explained in the specification beginning at page 2, line 1, "[a] common problem associated with the use of such bone fixation plates is a tendency of the bone screws to 'back out' or pull away from the bone onto which they were fixed. This problem occurs primarily due to the normal motion of the body and the spine. Since the spine is a very dynamic entity and is constantly moving, this problem is especially prevalent in areas of high stress such as the spine. Once the screw becomes loose and pulls away from the bone, the head of the screw can rise above the surface of the bone fixation plate and even work its way completely out of the bone. This creates a number of potentially serious problems given the number and proximity of blood vessels and other critical structures near the locations of spinal fixation plate assemblies."

The bone plate assembly of the presently claimed invention includes a base plate 12, 12". Referring to the specification beginning at page 9, line 23, the base plate 12, 12" can vary in size and shape. For example, the base plate 12 can be curved, as depicted in FIG. 7, to match the curvature of the spinal column or may be completely flat. The base plate 12, 12" includes at least one aperture 14 extending through an upper surface 13 of the base plate 12 and through a lower surface 15. The upper surface 13 is the location of the initial insertion of the bone screws 18 and is not touching any bone surface thereon. The lower surface 15 is closest to the spinal column and typically touches the surface of the bones to which the base plate 12 is affixed.

As explained in the specification beginning at page 10, line 24, the apertures 14 of the bone plate assembly 10 are configured to allow for the insertion of a screw retaining mechanism 16, 16' over the bone screw 18 that is extended through the aperture 14 of the bone plate assembly 10. The screw retaining mechanism 16 partially covers at least a portion of the screw 18 to prevent the screw 18 from backing out from its fixed position within the bone and from within the

aperture 14 extending therethrough within the base plate 12 of the bone plate assembly 10.

As explained beginning at page 11, line 25, the screw retaining mechanism 16' may be a snap ring as shown in FIGS. 2A and 2B. The ring includes an outer cylindrical portion 24 with a flange 26 radially extending outward. A hole or aperture 22' is drilled through the screw retaining mechanism 16' with the location of the center point of that hole or aperture 22' eccentric to the center point of the outer cylindrical portion 24. The ring is then split to form a gap 28 and thus creates a screw retaining mechanism 16' that is substantially "C" shaped. As a result, placement of the ring into the machined aperture 14 of the base plate 12 occurs by simply squeezing the ring so that the gap 28 is reduced. The ring then is mounted into the aperture 14 and the pressure is released from the ring to allow the ring to spring open. The ring is now affixed and mounted within the aperture 14.

FIG. 4 shows a close up of the bone plate assembly 10" wherein the screw retaining mechanism 16" is mounted within the aperture 14" of the base plate 12" with the bone screw 18 extending therethrough. FIG. 4 illustrates the screw retaining mechanism 16" in its locked position. As shown therein, a portion of the screw retaining mechanism 16" covers at least a portion of the screw head 20, thereby preventing the screw 18 from backing out of the base plate 12" and the fixed position within the bone. To unlock the retaining mechanism 16", it is rotated until the aperture 22' is concentric with the aperture 14".

As set forth in the pending independent apparatus claim 61, the presently claimed invention relates to a bone plate assembly utilizing at least one bone screw for fixation of adjacent bones of a spine as generally shown in Figs. 2-5 and 21B.

The bone plate assembly of the presently claimed invention includes a base plate 12, 12". Referring to the specification beginning at page 9, line 23, the base plate 12, 12" can vary in size and shape. For example, the base plate 12 can be curved, as depicted in FIG. 7, to match the curvature of the spinal column or may be completely flat. The base plate 12, 12" includes at least one aperture 14 extending through an upper surface 13 of the base plate 12 and through a lower

surface 15. The upper surface 13 is the location of the initial insertion of the bone screws 18 and is not touching any bone surface thereon. The lower surface 15 is closest to the spinal column and typically touches the surface of the bones to which the base plate 12 is affixed.

As explained in the specification beginning at page 10, line 24, the apertures 14 of the bone plate assembly 10 are configured to allow for the insertion of a screw retaining mechanism 16, 16' over the bone screw 18 that is extended through the aperture 14 of the bone plate assembly 10. The screw retaining mechanism 16 partially covers at least a portion of the screw 18 to prevent the screw 18 from backing out from its fixed position within the bone and from within the aperture 14 extending therethrough within the base plate 12 of the bone plate assembly 10.

As explained beginning at page 11, line 25, the screw retaining mechanism 16' may be a snap ring as shown in FIGS. 2A and 2B. The ring includes an outer cylindrical portion 24 with a flange 26 radially extending outward. A hole or aperture 22' is drilled through the screw retaining mechanism 16' with the location of the center point of that hole or aperture 22' eccentric to the center point of the outer cylindrical portion 24.

As explained beginning at page 16, line 30, an added insert 74 is placed within base plate 12. This insert 74 has the appropriate machined grooves, tabs, extensions, spherical seats, and other features required to accommodate the screw retaining mechanisms 16. The advantage of the machined insert 74 is that the insert 74 is machined accordingly as opposed to machining the entire base plate 12. The base plate 12 merely needs to be punched-out, cut, or formed to provide a hole 76 in which to place the insert 74 therein. This results in increased compatibility with currently existing base plates 12 and also increases the various combinations of screw retaining mechanisms 16, machined inserts 74, and base plates 12 that can be formed. This variation is further illustrated in FIG. 21, wherein FIG. 21A shows the base plate 12 with a round hole 76, FIG. 21B shows the insert 74, and FIG. 21C shows the screw retaining mechanism 16. The ring may be placed into the insert 74, previously mounted into the aperture 14. The ring is now affixed and mounted within the insert 74 which in turn is mounted within the aperture 14.

The retaining mechanism changes from a locked position to an unlocked position by simply rotating the disc about the center of the outer diameter of the aperture 14. In its locked position, the screw retaining mechanism 16 partially covers at least a portion of the screw head 20 to prevent the screw head 20 from backing out. While in the unlocked position, the screw retaining mechanism 16 allows for easy access to the screw head 20 to remove it from the base plate 12 and fixed bone location therein. The aperture 22 located within the screw retaining mechanism 16 changes from an aligned position with the screw head 20 to a non-aligned position that partially covers at least a portion of the screw head 20 therein.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1, 8, 10 and 15-17 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Michelson.

B. Whether claim 21 is unpatentable under 35 U.S.C. § 103(a) as unpatentable over Michelson in view of Campbell et al.

C. Whether claim 61 is unpatentable under 35 U.S.C. § 103(a) as unpatentable over Michelson in view of Park.

VII. ARGUMENT

A. Rejection Under 35 U.S.C. §102(b) Based on U.S. Patent No. 6,138,550

Claims 1-8, 10, 15-17 and 61 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,138,550 (Michelson).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Independent claim 1 recites a bone plate assembly comprising: "a base plate including at least one aperture defining a through opening extending through the base plate; and a screw retaining mechanism mounted and rotatable within said aperture between locked and unlocked positions relative to said through opening for preventing the bone screw from backing out from said base plate, wherein said screw retaining mechanism includes a center axis and an internal opening eccentric to said center axis and having a ring at least substantially thereabout, and wherein said screw retaining mechanism is rotatable within said aperture about said center axis between said locked and unlocked positions, wherein said internal opening of said screw retaining mechanism is eccentric with said through opening of said base plate when in said locked position and said internal opening of said screw retaining mechanism is concentric with said through opening of said base plate when in said unlocked position."

Michelson does not teach each limitation each and every limitation of the claimed invention. The Office Action cites to element 20 (Figs. 10 and 11), element 508 (Fig. 64) or element 522 (Fig. 66) as corresponding to the claimed retaining mechanism, with cutouts 22, 510 and 524, respectively, corresponding to the claimed eccentric openings. As shown in Figs. 10, 11, 64 and 66, the cutouts 22, 510 and 524 of Michelson are not internal openings having a ring at least substantially thereabout. To the contrary, they are external cutouts that extend less than 180°. As such, even in the locked position, these elements 20, 508 and 522

overlie only a portion of the screw head, leaving room for the screw to become dislodged.

In response to such arguments, the Office Action indicates on page 5, that "the recitation of an 'internal opening' is deemed disclosed by Michelson. Specifically, the hole is cut into the device towards the center and is partially surrounded by a ring structure of the retaining mechanism." The Office Action provides no support for the external cutouts being considered internal openings. Such a conclusion can only be based on improper hindsight in view of appellants' disclosure. Furthermore, the Office Action acknowledges that that cutouts, even if they could be considered internal openings, are only partially surrounded by a ring structure. The Office Action does not attempt to overcome the deficiency of such cutouts extending less than 180°.

The cited references, alone or in any reasonable combination, fail to teach each and every limitation of the claimed invention. It is respectfully submitted that independent claim 1 is in condition for allowance. Claims 2-8, 10, 15-17 and 21 each depend from claim 1 and are therefore allowable for at least the reasons set forth above. Additionally, withdrawn claims 13 and 14 each ultimately depend from independent claim 1 and should be reinstated and allowed as dependent upon an allowable generic claim.

Appellants respectfully request reconsideration and reversal of the rejection of claims 1-8, 10, and 15-17 under 35 U.S.C. §102(b).

B. Rejection Under 35 U.S.C. §103(a) Based on U.S. Patent No. 6,138,550 in View of U.S. Patent No. 6,602,255

Claim 21 stands rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 6,138,550 (Michelson) in view of U.S. Patent No. 6,602,255 (Campbell et al.).

"To establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim

limitations.” M.P.E.P. §2143. Additionally, as set forth by the Supreme Court in KSR Int’l Co. v. Teleflex, Inc., No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

Claim 21 depends from independent claim 1 and incorporates all of the limitations thereof. As set forth above, Michelson fails to teach or suggest each limitation of independent claim 1, and therefore, dependent claim 21. Campbell et al. is cited for the limited teaching of a collapsible c-ring. Campbell et al. does not overcome the shortcomings of Michelson described above.

Appellants respectfully submit that claim 21 is in condition for allowance. Appellants respectfully request reconsideration and reversal of the rejection of claim 21 under 35 U.S.C. §103(a).

C. Rejection Under 35 U.S.C. §103(a) Based on U.S. Patent No. 6,138,550 in View of U.S. Patent No. 5,057,111

Claim 61 stands rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 6,138,550 (Michelson) in view of U.S. Patent No. 5,057,111 (Park).

“To establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations.” M.P.E.P. §2143. Additionally, as set forth by the Supreme Court in KSR Int’l Co. v. Teleflex, Inc., No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

Independent claim 61 recites a bone plate assembly comprising “a base plate including at least one hole extending therethrough; insert means operatively engaged within said at least one hole for accommodating the bone screw and a screw retaining mechanism having an internal, eccentric opening, the screw retaining mechanism mounted and rotatable within said insert means between locked

and unlocked positions relative to said insert means for preventing the bone screw from backing out from said base plate.”

The Office Action acknowledges that Michelson does not disclose an insert and cites Park as teaching an insert member 28 {sic}. Appellants respectfully submit that even if the references were combinable, they fail to teach each and every limitation of the claimed invention.

Park explains at column 8, lines 15-42, that:

Polymer member 28 has a plate contacting surface 30 that is configured to contact a plate opening surface 18', 20' of a respective relaxation opening 18, 20 in an uninterrupted fashion from the top plate surface to the bottom plate surface. . . .

As shown for example in FIG. 5, polymer member 28 also has an attaching means contacting surface 32 which is disposed to contact the attaching means, such as a screw, when device 10 is in use for bone fracture healing. Attaching means contacting surface 32 is preferably configured to conform to at least the continuous portion of the outer surface of the attaching means that resides within the relaxation opening when the attaching means extends through the relaxation opening to attach the plate to the bone. When attaching means contacting surface 32 is initially disposed against the outer surface of the attaching means, there preferably are no gaps or voids between attaching means contacting surface 32 and the outer surface of the attaching means.

(emphasis added). As explained herein, Park provides no provision for receiving a retaining mechanism. To the contrary, Park further explains at column 10, lines 23-63, that:

The polymer member is formed preferably either of viscoelastic material or resorbable material. . . .

When viscoelastic material composes the polymer member, this material deforms under load and creeps out of the relaxation opening and over top surface 14 of plate 12. In this way, the section of the attaching means contacting surface near the top of the attaching means moves away from the gapless contact with the attaching means that characterized the initial installation of device 10 to the fractured bone. Thus, a change in the thickness profile of the polymer member between the upper portion of the attaching means and the opening surface of the relaxation opening occurs. This in turn results in a loosening of the fit of the attaching means in the opening formed by the attaching means contacting surface of the polymer

member. Accordingly, as the fit becomes looser, the device gradually transfers load to the bone during the healing process and substantially prevents the stress-shielding of the bone that occurs with the use of conventional bone fracture plates. . . .

When resorbable material composes the polymer member, the body tissue surrounding device 10 gradually absorbs this material. This reduces the size of the polymer member and results in a reduced thickness profile of the polymer member between the attaching means and the plate opening surface of the relaxation opening. Thus, both the thickness profile of the polymer member and the separation between the attaching means and the opening surface change.

(emphasis added). Park teaches away from the claimed invention in that it is intended to intentionally loosen the retention of the attaching means.

Furthermore, even if polymer members as taught by Park were positioned in the openings 6, 502, 508 of Michelson, they would be configured to directly receive and be in contact with the screw head as taught by Park. The retaining mechanisms would not be mounted in and rotatable relative to such polymer members as recited in claim 61.

Furthermore, neither Michelson teaches or suggests a screw retaining mechanism having an internal, eccentric opening, as explained above with respect to claim 1. Park does not teach or suggest any screw retaining mechanism, but instead teaches away from such.

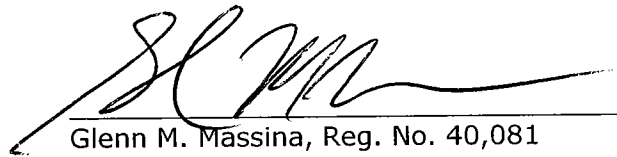
The cited references, alone or in any reasonable combination, fail to teach each and every limitation of the claimed invention. It is respectfully submitted that independent claim 61 is in condition for allowance. Appellants respectfully request reconsideration and reversal of the rejection of claim 21 under 35 U.S.C. §103(a).

VIII. CONCLUSION

In view of the arguments set forth above, all pending claims are patentable over the cited references. The rejection of all of the pending claims of record should therefore be reversed with instructions to issue a Notice of Allowability. Moreover, Appellants request reconsideration and allowance of claims 13 and 14, which are withdrawn to a nonelected species, upon the allowance of the generic claim. Such actions are respectfully requested.

Respectfully Submitted,

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Enclosures: Claims Appendix
Evidence Appendix
Related Proceedings Appendix

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The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

CLAIMS APPENDIX

1. A bone plate assembly utilizing at least one bone screw for fixation of adjacent bones of a spine comprising: a base plate including at least one aperture defining a through opening extending through the base plate; and a screw retaining mechanism mounted and rotatable within said aperture between locked and unlocked positions relative to said through opening for preventing the bone screw from backing out from said base plate, wherein said screw retaining mechanism includes a center axis and an internal opening eccentric to said center axis and having a ring at least substantially thereabout, and wherein said screw retaining mechanism is rotatable within said aperture about said center axis between said locked and unlocked positions, wherein said internal opening of said screw retaining mechanism is eccentric with said through opening of said base plate when in said locked position and said internal opening of said screw retaining mechanism is concentric with said through opening of said base plate when in said unlocked position.
2. The bone plate assembly according to claim 1, wherein said base plate further includes a longitudinal axis defined by a first end and a second end and a length along said axis sufficient to span between the adjacent vertebrae, said base plate further including an upper and a lower surface, said lower surface being adapted to engage the bones.
3. The bone plate assembly according to claim 2, wherein said base plate is curved transverse to said longitudinal axis to conform the bone plate to the curvature of the vertebrae.
4. The bone plate assembly according to claim 1, wherein said at least one aperture is selected from the group consisting of a circular hole, a bore, a slot, and polygonal opening.
5. The bone plate assembly according to claim 3, wherein said bore includes at least one internal recess disposed in at least one of said upper and lower surfaces of said plate.

6. The bone plate assembly according to claim 3, wherein said at least one aperture disposed between said ends of said bone fixation plate is disposed along said longitudinal axis of said bone fixation plate.
7. The bone plate assembly according to claim 3, wherein said at least one aperture is an elongated slot disposed at a substantially acute angle with respect to said longitudinal axis of the base plate.
8. The bone plate assembly according to claim 4, wherein said aperture includes an outer edge.
9. (Cancelled)
10. The bone plate assembly according to claim 1, wherein said screw retaining mechanism is selected from the group consisting of a washer, ring, clip, and disk.
- 11.-12. (Cancelled)
13. The bone plate assembly according to claim 10, wherein said screw retaining mechanism includes a tab for engaging said at least one groove located along an outer edge of said aperture of said base plate.
14. The bone plate assembly according to claim 13, wherein said tab engages said at least one groove to provide for said locked and unlocked positions.
15. The bone plate assembly according to claim 1, wherein said screw retaining mechanism partially blocks a portion of the screw disposed in said through opening thereby defining said locked position.
16. The bone plate assembly according to claim 1, wherein said screw retaining mechanism does not block a portion of the screw disposed in said through opening thereby defining said unlocked position.
17. The bone plate assembly according to claim 1, wherein said screw retaining mechanism is flush with an outer surface of said base plate.
- 18.-20. (Cancelled)

21. The bone plate assembly according to claim 1, wherein said aperture is defined by a wall including a groove radially and outwardly recessed in said wall and said screw retaining mechanism is within said groove and said screw retaining mechanism is a C-shaped washer that is collapsible to be inserted into said groove of said aperture.

22.-60. (Cancelled)

61. A bone plate assembly utilizing at least one bone screw for fixation of adjacent bones of a spine comprising:

a base plate including at least one hole extending therethrough;

insert means operatively engaged within said at least one hole for accommodating the bone screw; and

a screw retaining mechanism having an internal, eccentric opening, the screw retaining mechanism mounted and rotatable within said insert means between locked and unlocked positions relative to said insert means for preventing the bone screw from backing out from said base plate.

62.-66. (Cancelled)

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EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None